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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,459	12/19/2001	Yasushi Watanabe	2500.9	2404

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[REDACTED] EXAMINER

YOUNG, MICAH PAUL

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1615

DATE MAILED: 06/02/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/913,459	WATANABE ET AL.
Examiner	Art Unit	
Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 March 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 15-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 15-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Acknowledgment of Papers Received: Supplemental Information Disclosure Statement filed 1/13/03, Amendment and Extension of Time filed 3/18/03.

Notice

The following action includes, new objections and rejections not previously made of record.

Specification

1. The disclosure is objected to because of the following informalities: In various locations throughout the specification, reference is made to the claims of the invention. This is improper form. It is required that applicant simply define the invention in the specification rather than referring to the claims of the invention. Further, after the amendment to the claims, the references to the claims in the specification are referenced to now canceled claims. In all the specification must be amended completely to remove all references to the claims of the invention.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 15-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new claims in the instant application comprise the limitation: "compressing the granulated materials without their surfaces being moistened." This was not claimed in the previously considered claims, nor has it been established in the specification. This limitations is an apparent attempt to overcome the art of record, yet sufficient definition of this limitation is lacking in the case.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto *et al.* (EP 0 745 382) in view Sangekar *et al.* (USPN 3957662). The tablet comprises saccharides, disintegrants, binders and surface-active agents. The process comprises making a fluidized bed, spraying an aqueous solution, drying it to make granules and compressing the granules into tablets.

5. Mizumoto *et al.* teaches a compressed tablet formulation comprising saccharides, binders and disintegrants. The tablet of the formulation uses two types of saccharides, high and low moldability. The saccharides of low moldability include lactose, mannitol, xylitol and the like.

Saccharides of high moldability include maltose, maltitol, sorbitol and oligosaccharides (pg 5, lin. 20 – 29). The binding agents include powdered acacia gelatin and the like. The reference further discloses a method that comprises making a fluidized bed, spraying an aqueous solution, drying it to create granules and compressing it to make the tablets (pg 9, lin. 30 – 58).

It is known in the art of tablet production that surfactants, can be used as lubricants in order to improve disintegration and dissolution. As established in Sangekar *et al.*, tablets containing surfactants are more easily dispersed and have better disintegration (Abstract; col. 2, lin. 18 – 34).

Also with regard to claims 15-20 which recited limitations as to how the tablets are obtained, these limitations are a process of making, yet a product is claimed. These claims are considered to be product-by-process claims, therefore these limitations are not considered. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

With regard to claims 23-25, which recite limitation as to the ratio of one type of saccharide to another, and concentration of the saccharides in the formulation, these limitation are not taken in to consideration. These recitations of optimal ranges can be determined through routine experimentation. The general combination of saccharides, binders, disintegrants, and surface-active agents is present in the prior art. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or

workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparations of various compressed tablet formulations having various amounts of the actives is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *In re Russell*, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971).

With this in mind one of ordinary skill in the art would have been motivated to follow the suggestions of Mizumoto and include the surfactants of Sangekar as lubricants in order to improve the disintegration and dissolution time of the compressed tablet formulation. It would have been obvious to one of ordinary skill in the art, at the time of the invention to follow the suggestions and knowledge in the art with an expected result of a compressed tablet with improved disintegration and dissolution time.

Response to Arguments

6. Applicant's arguments with respect to claims 1-14 and new claims 15-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young
May 30, 2003


CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500